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**A Cost-effectiveness Analysis of Reverse Total Shoulder Arthroplasty versus
Hemiarthroplasty for the Management of Complex Proximal Humeral Fractures in the
Elderly**

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ABSTRACT

Objectives

There is ongoing debate regarding the optimal surgical treatment of complex proximal humeral fractures in elderly patients. Using a cost-utility analysis, the aim of this study was to evaluate the cost-effectiveness of reverse total shoulder arthroplasty (RTSA) compared to hemiarthroplasty (HA) in the management of these fractures.

Methods

Decision trees and Markov modelling were derived based on data from the published literature. A single-payer perspective with a willingness to pay threshold of CAD \$50,000 and a lifetime time horizon was used. The incremental cost-effectiveness ratio (ICER) was used as the study's primary outcome measure.

Results

In comparison to HA, the incremental cost per QALY gained for RTSA was \$13,679. One-way sensitivity analysis revealed the model to be sensitive to the RTSA implant cost and the RTSA procedural costs. The ICER of \$13,679 is well below the WTP threshold of \$50,000 and probabilistic sensitivity analysis demonstrated that 92.6% of model simulations favored RTSA.

Conclusions

Our economic analysis found that RTSA for the treatment of complex proximal humeral fractures in the elderly is the preferred economic strategy when compared to HA. The ICER of RTSA is well-below standard willingness to pay thresholds, and its estimate of cost-effectiveness is similar to other highly successful orthopaedic strategies such as total hip arthroplasty for the treatment of hip arthritis.

INTRODUCTION

Fractures of the proximal humerus are common debilitating fractures in the elderly. Due to the impaired bone quality and frailty in this patient population there is an increased incidence of complex and unstable proximal humeral fractures [1, 2]. Although the benefits of surgical interventions remain controversial [3], locked plate fixation has become a standard surgical treatment for many fracture patterns [4-6]. Despite the preference for internal fixation [7], fractures with complex patterns and calcar comminution can be difficult to successfully treat with plate fixation [6, 8-11]; as a result, arthroplasty has increasingly been used to manage these complex fractures in elderly patients who have low functional demands [12-17].

Successful hemiarthroplasty (HA) can be challenging as anatomic healing of the tuberosities is essential in order to improve the postoperative functional outcome [16]. Reverse total shoulder arthroplasty (RTSA), in contrast, has gained recent popularity because its success can be independent of tuberosity malposition or rotator cuff integrity. Although this represents a substantial design advantage, widespread adoption of RTSA has been tempered by high implant costs and sparse salvage options for failure [17]. There is ongoing debate in orthopaedic surgical community on whether RTSA or HA is the preferable management strategy of complex displaced proximal humeral fractures in elderly patients.

Recently, several clinical trials and systematic reviews [18-27] have compared both interventions with regard to their functional outcomes and their associated risks for complications. Briefly, these studies have suggested improved functional outcomes with a higher rate of complications in the RTSA groups. The results of these studies enhance our understanding of the clinical effectiveness of these treatments; however, they do not inform the economic value of each strategy. With constrained health budgets, consideration of the cost-effectiveness of management strategies is becoming increasingly more important for both surgeons and policy makers. Therefore, the aim of the current study is to evaluate the cost-effectiveness of RTSA compared with HA in the treatment of complex proximal humeral fractures in elderly patients. The following economic evaluation is based on the assumption that the treating surgeon has opted for surgical treatment, in particular, joint arthroplasty due to the complexity of the fracture. Therefore, a non-operative comparison was not included in the model and the included fracture pattern is deemed inappropriate for treatment using internal plate fixation.

METHODS

Overview

Based on data from published literature, we conducted a cost–utility analysis using decision tree and Markov modelling. A single-payer Canadian provincial government perspective (Ontario Ministry of Health) and a lifetime time horizon were used. The incremental cost-effectiveness ratio (ICER) was the primary metric of cost-effectiveness. We conducted multiple sensitivity analyses to explore the robustness of our findings. To determine which of the treatments would be the economically preferred intervention, we used a willingness-to-pay (WTP) threshold of \$50,000 per incremental QALY gained [28].

Model Overview

TreeAge Pro 2011 (TreeAge Software, Inc, Williamstown, MA) was used to construct a decision tree for the first two years of the model (**Figure 1**) followed by a Markov model for the remainder of the lifetime. At the end of each node of the decision tree, a Markov process starts which extends the time horizon in the decision tree for the remainder of a patient's lifespan (**Figure 2**). Briefly, all individuals enter the Markov model with their health state from the end of the 2-year horizon and then undergo one-year cycles in the Markov model. With every one-year cycle, individuals either maintain their current health state or transition to a different state.

Base Case Scenario

The base case scenario provides the clinical context for the economic analysis. The analysis was performed based on a 72-year-old female patient with a complex proximal humerus fracture and general health suitable for either arthroplasty procedure (American Society of Anaesthesiologists Physical Status Classification 1 or 2). The base case demographics were chosen to represent the most commonly encountered clinical scenario based on age and gender [20, 21].

Literature Search

We conducted a comprehensive search of the published literature to identify: 1) systematic reviews that compare RSTA versus HA and report complication rates and functional outcomes, and 2) clinical studies that evaluate the clinical efficacy of RTSA and HA for the treatment for complex proximal humeral fractures in elderly patients. Our literature search identified four systematic reviews [18-21] and 21 clinical studies including 13 single intervention case series [12-17, 29-35], five retrospective comparative studies [24-27,

36], one prospective cohort study [23], and one randomized controlled trial [22]. The studies identified from our literature search informed the complication rates and the assignment of the health states within the model.

Complication Rates

Complication rates were then derived from the studies identified in our literature search (**Table 1**). Complications were differentiated as either not requiring revision surgery (e.g. neuropraxia, cellulitis treated with antibiotics, dislocation amenable for closed reduction, etc.) or requiring revision surgery (e.g. deep infection, recurrent dislocation, implant loosening, etc.). Revision surgery was then classified as either minor surgery (e.g. wound excision, irrigation with change of the mobile components, etc.) or major surgery (e.g. implant revision with change of stem, glenoid component, etc.). The early complication rate for RTSA was 15% [18-21], with 40% of these early complications cases requiring revision surgery [18-21]. For HA, the early complication rate was 10% [12, 18-21], with 50% of cases requiring revision surgery [12, 18-21]. If an early complication required surgical intervention, the probability of a major revision was estimated to be 50% in both treatment groups [12, 18-21].

For the late complications within the Markov modelling, estimates for the annual complication rates were based on values reported in large meta-analyses [12, 18, 19, 37]. As the Markov model begins two years after implantation of the prosthesis and the studies included into the meta-analyses had a mean follow up of about 3 to 4 years, the estimates were modified in order to account for a longer interval (i.e. the mean patient's survival). The annual probability of a late infection was assumed to be 0.2% [12, 18, 19, 37] and aseptic loosening was 0.5% [12, 18, 19]. The probability of sustaining a periprosthetic fracture was estimated at 0.1% per year [12, 18, 19]. We also assumed that patients with a late complication would spend one-year in an impaired health state before they return to either their previous health state (post-periprosthetic fracture or aseptic loosening) or to a health state of "poor function/no pain" after late infection.

Health States

All patient outcomes were defined by five health states: "excellent function", "good function", "poor function/no pain", "poor function/pain", and "death". We estimated that the majority of patients who required major revision surgery would have poor functional outcomes [22]. For the remainder of patients, the health states were defined by a patient's forward shoulder flexion and pain. Beta distributions were used to estimate the proportion of individuals with elevation <90°, 90° to 120°, and >120° without chronic pain; as

well as the distribution of individuals with chronic pain scores greater than 5/10 [38]. If a patient had pain >5/10, it was assumed the patient also had poor function; conversely, it was assumed that no patients would have pain >5/10 and still be described as good or excellent function. The description of each health state and its probability within the decision tree are listed in **Table 2**.

Patients with a health state of “excellent function”, “good function” or “poor function/no pain” who have a late complication were modelled to transition to a health state of “poor function/pain”. Individuals with a health state of “poor function/pain” who have a complication transition to a sixth temporary health state (“very poor function/pain”) added for modelling this specific scenario. As general health is expected to deteriorate over time, 2% of the individuals in each health state group were modelled to transition to an inferior state per year. The probability of death at any point in the model was estimated based on Canadian Census life tables and represents age-specific all-cause mortality risk [39].

Utility Values

Utility values were derived from patient outcomes in several high-quality studies [12, 31], and cross-referenced with EQ-5D values reported in a third study that reported 2-year outcomes on one the two interventions [12]. The authors used clinical experience to confirm the face validity of the estimates. Clinically plausible ranges for each outcome were included with model variation in the patient population at each health state. The utility values for each of the health states within the model are listed in **Table 1**. QALYs were then calculated based on the duration of time spent in a particular health state multiplied by the utility value of the given health state.

Estimation of Costs

All costs are reported in 2014 Canadian dollars (CAD), and both costs and health state values were discounted 5% annually, following Canadian guidelines [41]. Hospital costs were estimated using data from a provincial government initiative that collects standardized case costing data from nearly 50 hospitals in Ontario, Canada (Ontario Case Costing Initiative) [42]. Billing costs for physician services were estimated using the Ontario Schedule of Benefits [43]. Implant costs were estimated based on regional pricing. To model conversions from HA to RTSA, we assumed that half of the early major revisions of HA would be conversions to RTSA; accordingly, the estimated implant cost for major revisions of HA were set to be the median cost of an HA and RTSA implants. Similarly, we assumed that late deep infections of HA were

accompanied by a loss of rotator cuff function and would be treated with an RTSA implant. All model cost estimates are listed in **Table 1**.

Calculation of the Incremental Cost-Effectiveness Ratio (ICER)

The ICER was calculated as the difference in costs between the two treatments (RTSA and HA) divided by the difference in quality-adjusted life years (QALYs) between the two treatments (RTSA and HA).

Sensitivity Analysis

In order to explore potential uncertainties in model variables, we conducted a one-way sensitivity analysis on the RTSA implant costs and a two-way sensitivity analysis on the RTSA implant costs and the RTSA early complication rate [44]. As the use of RTSA in the treatment of proximal humerus fractures has not been fully established, it is anticipated that the implant costs will decrease with time and that early complications will become less frequent with increasing surgical experience with this technique. We chose a RTSA implant cost range from \$1,000 to \$10,000 for the sensitivity analysis. The base case RTSA procedural costs excluding the implant were estimated to be \$21,059 (**Table 1**). We chose a range from \$8,000 to \$40,000 for the sensitivity analysis. With regard to the early complications, a rate of 15% was modelled for the RTSA treatment arm based on the literature [18-21], and a range from 0% to 35% was used for sensitivity analysis.

To account for inherent uncertainty in all variable estimates and to further evaluate the robustness of the model, a probabilistic sensitivity analysis (PSA) was performed using a Monte Carlo simulation of 100,000 runs. In PSA, all model parameters are assigned a probability distribution, and in each run of the model, a random sample from those distributions is drawn. Beta distributions were used for probabilities and gamma distributions were used for costs and health state values [45].

RESULTS

Incremental QALYs, Costs, and Cost Effectiveness

Based on our lifetime model, the treatment of a proximal humerus fracture in an elderly population with HA was associated with a cost of \$18,348 and 5.76 QALYs gained. Treatment of this fracture with RTSA resulted in a cost of \$24,219 and 6.19 QALYs gained (**Table 3**). While RTSA was associated with \$5,871 more cost than HA, it also provided 0.43 more QALYs over the patient's lifetime when applied to the base case scenario. Therefore, the incremental cost per QALY gained for RTSA was \$13,679.

Sensitivity Analyses

One-way sensitivity analysis revealed the model to be sensitive to the RTSA implant cost and the RTSA procedural costs. RTSA treatment becomes the more cost-effective treatment, compared to HA, within two years of the initial procedure if the implant cost is less than \$5,674 or the overall procedural costs for RTSA remain less than \$12,733. When costs are held constant in the model, the RTSA early complication rate would have to exceed 38% before HA provided more QALYs. Two-way sensitivity analysis suggested RTSA to be cost-effective compared to HA within the first two years of surgery with an early complication rate as high as 25% (if RTSA implant cost was approximately \$3,000); or conversely, RTSA implant cost could be as high as \$8,500 if its early complication rates were 5% (**Figure 3**).

Probabilistic sensitivity analysis demonstrated that 92.6% of model simulations favored RTSA at the \$50,000 WTP threshold (**Figure 4**). The cost-effectiveness acceptability curve also demonstrates that RTSA is favored in the majority of simulations with a WTP threshold greater than \$16,000 (**Figure 5**).

CONCLUSIONS

The aim of this economic study was to determine the cost-effectiveness of reverse total shoulder arthroplasty (RTSA) compared with hemiarthroplasty (HA) in the treatment of complex elderly proximal humeral fractures. A cost–utility analysis from a single-payer perspective was performed using data from the current literature and decision tree and Markov modelling techniques. The results of this analysis suggest that RTSA is more expensive but also more effective; with an ICER of \$13,679 per incremental QALY gained. Therefore, RTSA is likely to be cost-effective compared to HA.

To the authors' knowledge, this is the first study comparing cost-effectiveness of RTSA versus HA in fracture patients. A previous cost-effectiveness analysis has been performed for the treatment of rotator cuff arthropathy, but not for the currently controversial management of proximal humerus fractures [46]. In the model by Coe et al, RTSA was the preferred treatment, as well, but using a much higher and less accepted WTP threshold. A second prospective economic study on rotator cuff arthropathy reported a cost-utility for RTSA between \$16,747/QALY and \$26,920/QALY (US dollars, USD) at two years postoperatively [47]. Both studies [44, 45] also recognized the high sensitivity of their models to the utility lost due to complications from the operation and the cost of the implant. A third economic study [48] compared HA and RTSA on basis of data from the Nationwide Inpatient Sample database (2011) and found RTSA to be an independent risk factor for inpatient morbidity, mortality, and hospital costs [48].

The complication rates for elective shoulder arthroplasty differ noticeably from the values known for arthroplasty in the treatment of proximal humerus fractures [18-21]. In addition, patients who have sustained a proximal humerus fracture are clearly more likely to have an impaired baseline neuromuscular coordination when compared to non-fracture patients selected for elective shoulder arthroplasty [49]. Hence, the present study provides important guidance on the economic value of arthroplasty options used to treat shoulder fracture patients.

A major strength of this study is its use of multiple data sources and meta-analysis data. In addition, many cost values were derived from the prospective multi-center Ontario Case Costing Initiative. Furthermore, the model's conclusions were highly stable across one-way, two-way, and probabilistic sensitivity analyses. Despite the robust nature of the model's results, the focus on the Canadian system limits the conclusions made to healthcare systems and populations with similar characteristics. For systems with larger healthcare

costs (such as the United States), the ICER is less likely to be cost-effective because the incremental costs between implants is typically larger; however, readers can use our model to determine how close the base case estimates are to their own healthcare system.

Other model characteristics must also be considered. This analysis was conducted from a single-payer perspective and did not account for indirect costs such as absence from work and need for nursing care. As this fracture most commonly affects elderly patients and the subsequent shoulder dysfunction of the injury has a tremendous impact on their general care dependency, it is likely that the patient and their caregiver will also incur considerable indirect costs associated to this injury.

In an ideal situation such an analysis would be based on very long-term studies comparing costs and outcomes of patients randomized to the two groups. However, such studies are simply not available at present, yet policy decisions still need to be made. Mathematical models are commonly used to assess and forecast the relative effectiveness and cost effectiveness of alternative treatment strategies using a synthesis of the best available evidence [50]. The results, including the uncertainty in the results, often guide policy decisions, assist physicians in comparing treatment strategies, and help clinicians design clinical studies.

In any cost-effectiveness analysis, the determinant of what treatment is economically preferred is highly dependent on the societal WTP threshold adopted. This study used a WTP threshold of \$50,000 CAD per incremental QALY gained, which is less than the commonly cited threshold of \$50,000 USD [28]. Other authors have even suggested higher thresholds to be appropriate [51,52]. With an incremental cost of only \$13,679 CAD per incremental QALY, RTSA proved to be clearly below all commonly accepted WTP thresholds, and was highly cost-effective when compared to HA. A treatment that provides an ICER of \$13,679 CAD would be categorized as a “recommended” medical intervention by the National Health Service in the UK [53] and is far below the commonly cited U.S. Medicare willingness to threshold for renal dialysis [52,54].

In conclusion, when comparing HA and RTSA in the treatment of complex proximal humeral fractures in elderly patients from a single-payer governmental perspective, RTSA approaches the willingness-to pay threshold within 2 years, but is overwhelmingly the preferred cost-effective strategy based on the lifetime horizon.

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FIGURE LEGEND

Figure 1 Decision tree representing the comparison of RTSA vs. HA for the treatment of complex proximal humerus fractures in elderly patients.

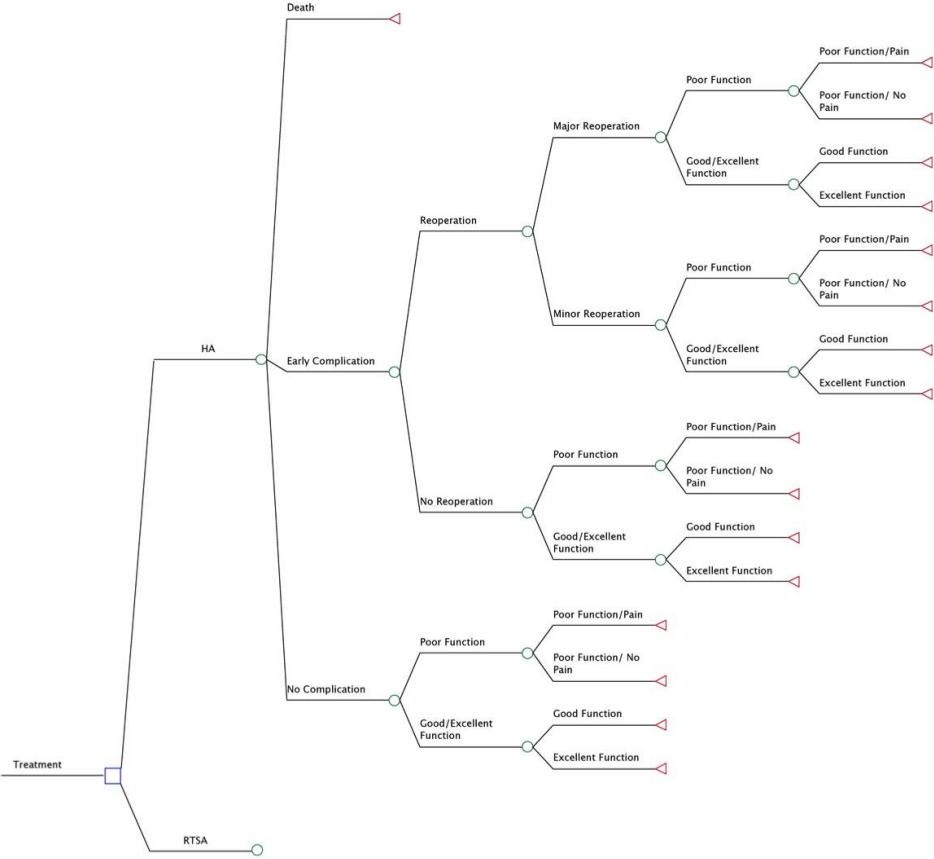
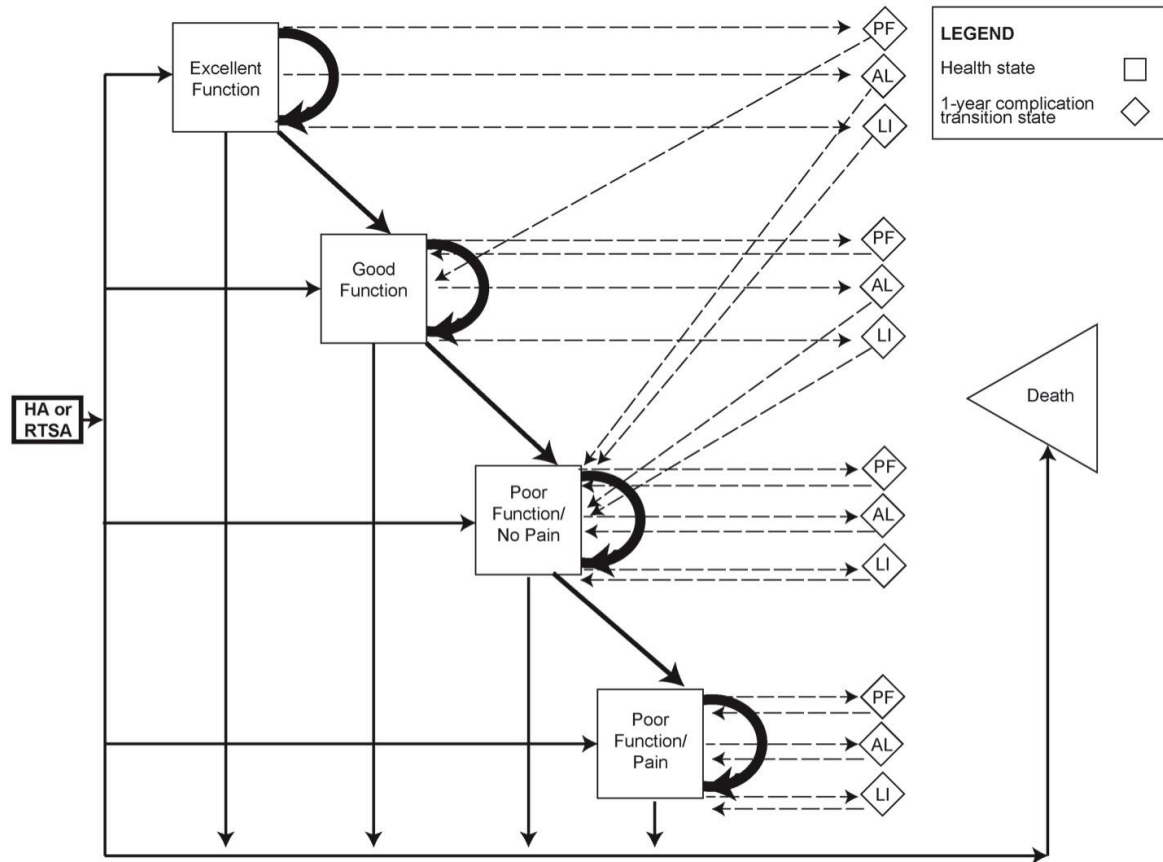


Figure 2 Markov model representing transitional health states. The Markov modeling process commences 2-years after the initial surgical treatment.



Note: HA, hemiarthroplasty; RTSA, reverse total shoulder arthroplasty; PF, periprosthetic fracture; AL, aseptic loosening; LI, late infection.

Figure 3 Results of two-way sensitivity analysis. The RTSA implant costs and the probability of an early complication from a RTSA treatment is varied.

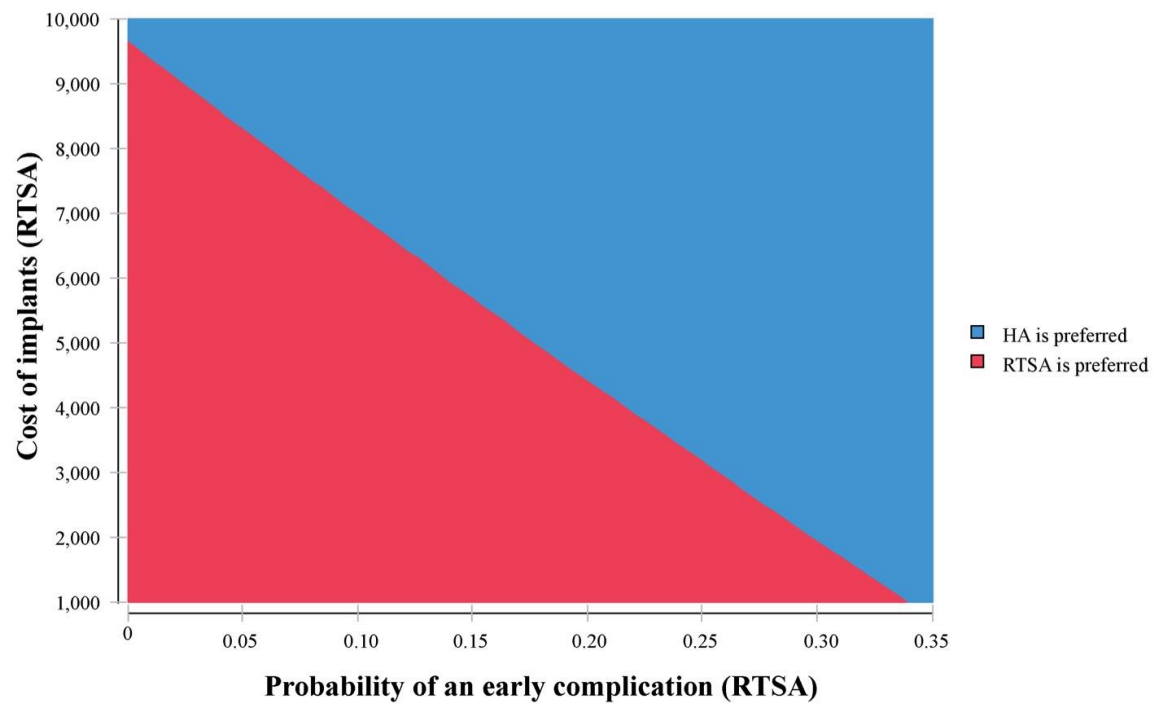


Figure 4 Results of Monte Carlo probabilistic sensitivity analysis. The incremental cost-effectiveness ratio for RTSA compared to HA is shown. A willingness to pay threshold of \$50,000 per incremental QALY (dashed line) and the 95% confidence interval (ellipse) are also shown.

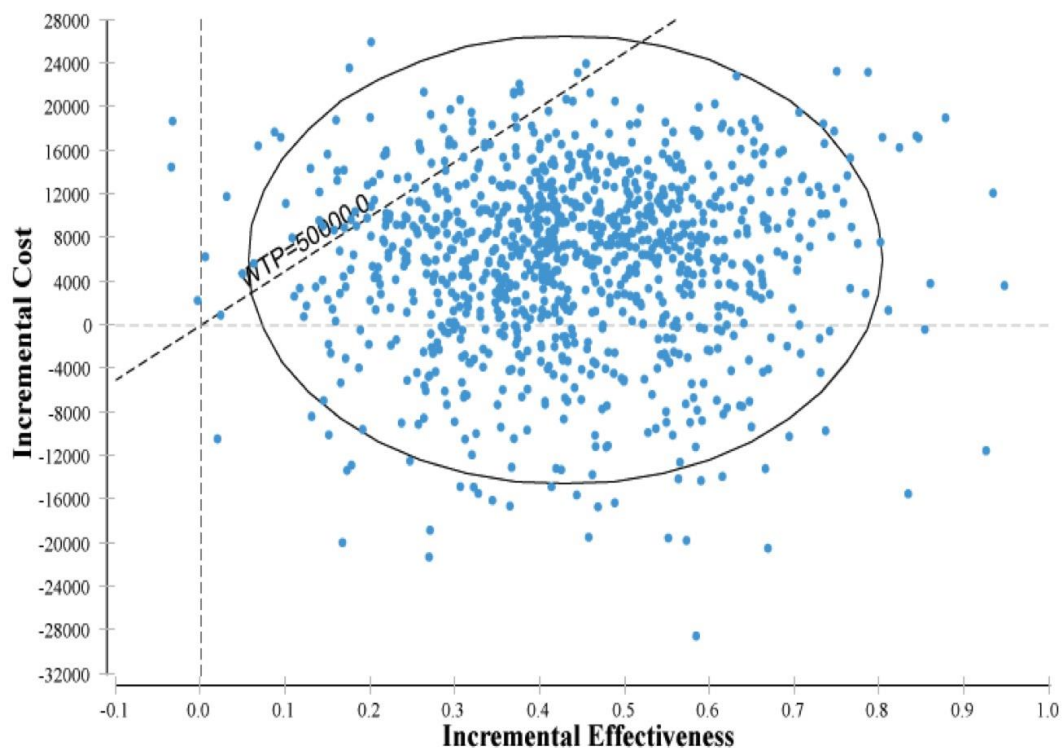


Figure 5 Acceptability curve of RTSA versus HA for the treatment of proximal humerus fractures in the elderly. This figure shows the fraction of the time RTSA or HA was cost-effective at various willingness-to-pay-per-QALY thresholds in the 100,000 Monte-Carlo simulations.

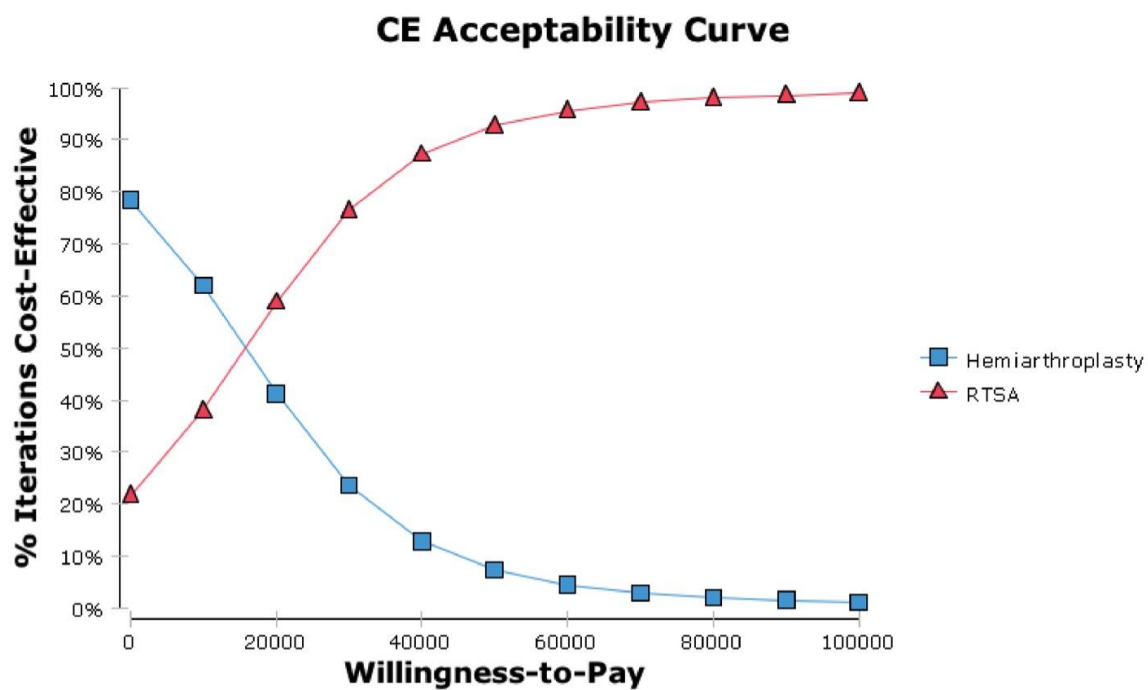


Table 1 Model parameters and ranges used in the probabilistic sensitivity analysis

Model parameters	Base Case Value	Range	Distribution	Source
Risk of complications (probability)				
<i>Hemiarthroplasty</i>				
Early complication	0.100	0.063 – 0.146	Beta	12,18-21
If early complication, requires reoperation	0.500	0.251 – 0.701	Beta	12,18-21
Annual risk of late infection	0.002	0.001 – 0.003	Beta	12,18,19,37
Annual risk of late late aseptic loosening	0.005	0.004 – 0.006	Beta	12,18,19,37
Annual risk of late late periprosthetic fracture	0.001	0.001 – 0.002	Beta	12,18,19,37
<i>Reverse Total Shoulder Arthroplasty</i>				
Early complication	0.150	0.091 – 0.220	Beta	18-21
If early complication, requires reoperation	0.400	0.230 – 0.570	Beta	12,18-21
Annual risk of late infection	0.002	0.001 – 0.003	Beta	12,18,19,37
Annual risk of late late aseptic loosening	0.005	0.004 – 0.006	Beta	12,18,19,37
Annual risk of late late periprosthetic fracture	0.001	0.001 – 0.002	Beta	12,18,19,37
Possible health states (utilities)				
Excellent Function	0.817	0.588 – 1.000	Gamma	12,31,40
Good Function	0.701	0.588 – 0.824	Gamma	12,31,40
Poor Function / No Pain	0.451	0.224 – 0.764	Gamma	12,31,40
Poor Function / Pain	0.217	0.126 – 0.344	Gamma	12,31,40
Very Poor Function/ Pain	0.154	0.007 – 0.300	Gamma	12,31,40
Cost estimates (\$CDN)				
<i>Hemiarthroplasty</i>				
Initial procedure	\$15,539	7,613 – 54,332	Gamma	42,43
Follow-up visit	\$94	38 - 172	Gamma	42,43

Short-term complications			Gamma	42,43
Major revision	\$21,446	4,642 – 48,161	Gamma	42,43
Minor revision	\$12,852	9,863 – 56,582	Gamma	42,43
Mid- and Long-term complications			Gamma	42,43
Late infection	\$20,196	6,900 – 41,883	Gamma	42,43
Aseptic loosening	\$19,196	6,711 – 42,912	Gamma	42,43
Periprosthetic fracture	\$14,556	5,274 – 30,750	Gamma	42,43

Reverse Total Shoulder Arthroplasty

Initial procedure	\$21,059	10,892 – 36,282	Gamma	42,43
Follow-up visit	\$94	38 - 172	Gamma	42,43
Short-term complications			Gamma	42,43
Major revision	\$21,307	12,345 – 35,324	Gamma	42,43
Minor revision	\$12,852	4,406 – 27,437	Gamma	42,43
Mid- and Long-term complications			Gamma	42,43
Late infection	\$22,307	14,436 – 31,499	Gamma	42,43
Aseptic loosening	\$21,307	14,437 – 31,499	Gamma	42,43
Periprosthetic fracture	\$16,943	11,168 – 24,874	Gamma	42,43

Table 2 Probability of each possible each health state two-years after surgical treatment

Short term outcomes	Probability
<i>Hemiarthroplasty</i>	
Excellent Function (Elevation >120°)	0.336
Good Function (Elevation 90° to 120°)	0.353
Poor Function / No Pain (Elevation <90°)	0.055
Poor Function / Pain (Elevation <90°, Pain >5/10)	0.222
Death	0.034
Reverse Total Shoulder Arthroplasty	
Excellent Function (Elevation >120°)	0.411
Good Function (Elevation 90° to 120°)	0.351
Poor Function / No Pain (Elevation <90°)	0.051
Poor Function / Pain (Elevation <90°, Pain >5/10)	0.153
Death	0.034

Table 2 Incremental cost-effectiveness of RTSA compared to HA

Treatment	Cost	QALY	ICER (Cost Per
			Incremental QALY Gained)
HA	\$18,348	5.76	
RTSA	\$24,219	6.19	\$13,679

